UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
KNOXVILLE

RALPH D. and BRENDA BRANCHE,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
ZIMMER, INC.,	)	Case No. 3:06-CV-234
	)	
Defendant.	)	

DEFENDANT ZIMMER, INC.'S SUPPLEMENTAL MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

The defendant, Zimmer, Inc. ("Zimmer"), respectfully submits this Supplemental Memorandum Of Points And Authorities In Support Of Motion For Summary Judgment ("Supplemental Memorandum").

I. INTRODUCTION

Zimmer filed its Motion For Summary Judgment and Memorandum Of Points And Authorities In Support Of Motion For Summary Judgment (collectively, "Motion For Summary Judgment") on July 21, 2008. On the eve of Zimmer's filing of the Motion For Summary Judgment, the plaintiffs, Ralph D. and Brenda Branche ("Plaintiffs"), served identical supplemental reports from William B. Campbell, Ph.D. ("Campbell"), and Philip J. Weis, P.E. ("Weis"), pursuant to Rule 26(a)(2)(B) of the Federal Rules Of Civil Procedure. The Supplemental Fed. R. Civ. [*sic*] 26(a)(2) Report Of William B. Campbell, Ph.D., and Supplemental Red. R. Civ. [*sic*] 26(a)(2) Report Of Philip J. Weis, P.E. (collectively, "Supplemental Reports"),[1] advance *for the first time* Plaintiffs' theory that Zimmer improperly

[1] The reports are referred to herein as the "Supplemental Campbell Report" and the " Supplemental Weis Report."

tested the design of the Natural Knee ("NK II") II Revision Stem. Supplemental Reports, attached as Exhibit A.

Though difficult to discern from the Supplemental Reports, Plaintiffs appear now to contend that Zimmer "negligently tested" the design of the NK II Revision Stem. However, neither the Tennessee Product Liability Act (the "TPLA") nor Tennessee common law recognize a cause of action for "negligent testing." For this reason alone, Zimmer is entitled to summary judgment on Plaintiffs' "negligent testing" claim.

In addition, should Plaintiffs intend to advance a claim for negligent design of the NK II Revision Stem, relying on the testing opinions expressed in the Supplemental Reports, Zimmer also is entitled to summary judgment for multiple reasons. First, as Zimmer explained in the Motion For Summary Judgment, Plaintiffs' negligent design claim requires Plaintiffs to prove that a defect in the design proximately caused Plaintiffs' alleged damages. Regardless of the factual basis for Plaintiffs' negligent design claim – Zimmer's testing or other conduct – Plaintiffs still have no expert medical testimony eliminating Mr. Branche's own deficient femoral bone stock or other medical causes as the proximate cause of the failure of the Device. Memorandum Of Points And Authorities In Support Of Summary Judgment ("Statement"), at 10 [Doc. 70]. For this reason alone, Zimmer is entitled to summary judgment on all of Plaintiffs' claims.

Second, and again as Zimmer explained in the Motion For Summary Judgment, Plaintiffs' negligent design claim requires proof of the existence of a defect, and Plaintiffs possess no such evidence. Because no evidence exists tending to show that a reasonably prudent manufacturer would not have marketed the NK II Revision System following Zimmer's testing or

that a reasonably prudent manufacturer would have tested the NK II Revision System differently than did Zimmer, Plaintiffs simply cannot meet their burden of proof.

Ultimately, Plaintiffs have no evidence proving that Zimmer was negligent in its testing of the NK II Revision Stem in any respect, much less the requisite evidence proving that the design was defective or Zimmer knew or should have known of the allegedly defective condition created by its conduct. To the contrary, Zimmer tested the design of the NK II Revision Stem in a manner consistent with decades of clinically successful implants and the industry standard at the time of sale, which neither Campbell nor Weis deny. For these reasons as well, Zimmer respectfully requests that the Court enter judgment as a matter of law.

II. BACKGROUND

Zimmer incorporates its Statement. Additional relevant procedural information includes:

Plaintiffs took the deposition of Zimmer's Rule 30(b)(6) witness, Charles Perrone, on July 18, 2008. Plaintiffs served their Fed. R. Civ. Pro. 26(a)(2) Expert Disclosures ("Plaintiffs' Expert Disclosures") on June 27, 2008, one week after their expert disclosure deadline. Plaintiffs' Expert Disclosures, attached hereto as Exhibit B. Subsequently, Plaintiffs served the Supplemental Reports on the evening of July 17, 2008. Supplemental Reports, *passim*. Zimmer deposed Campbell and Weis on July 22 and 23, respectively.[2]

[2] Neither Campbell nor Weis possess a reliable scientific methodology required by *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579 (1993) and Evidence Rule 702. Likewise, the witnesses are not qualified within Evidence Rule 702 to offer many of the opinions proferred. For these reasons, among others, Zimmer intends to move to exclude the testimony of Campbell and Weis by separate motion pursuant to the Court's Amended Scheduling Order.

The Supplemental Reports include new opinions by Campbell and Weis, which were not included in Plaintiffs' Expert Disclosures. Specifically, the witnesses opine that Zimmer's testing of the NK II Revision Stem was "inadequate." Zimmer moved to strike the Supplemental Reports because, *inter alia*, the opinions in the Supplemental Reports are based on documents Zimmer produced months before Plaintiffs' June 20, 2008, deadline for making expert disclosures and are otherwise insufficient under Rule 26(a)(2)(B). *See* Defendant Zimmer, Inc.'s Reply In Support Of Motion To Strike Plaintiffs' Rule 26(a)(2)(B) Expert Disclosures And To Exclude Plaintiffs' Experts ("Motion To Strike") [Doc. 77]. The Motion To Strike is currently pending before the Court.

Within the Supplemental Reports, Campbell and Weis opine that the NK II Revision Stem was not subject to adequate testing such that material fatigue fractures would be eliminated. Supplemental Campbell Report at 1; Supplemental Weis Report at 1. They assert that the Device suffered a fatigue fracture at the "same general location" as the fatigue fractures in Zimmer's fatigue testing. *Id.* Campbell and Weis opine that Zimmer did not take adequate steps address the fatigue fractures following testing, *id.*, and that Zimmer did not appropriate address its test results, *id.* at 2. Both experts state that Zimmer did not "properly investigate" variables in the NK II Revision System, such as the stem/taper fit, taper tolerances, and the thread depth of the taper locking screw. *Id.* at 2. Both experts state that in their supplemental reports that the medical device industry generally followed standard sets by the American Society of Testing and Materials ("ASTM"), but that there is no indication Zimmer used ASTM standards for testing the NK II Revision System. *Id.* Ultimately, both experts conclude that Zimmer should have revised its design of the NK II Revision System based on the fatigue failure tests. *Id.* at 3.

In his deposition on July 22, 2008,[3] Weis admitted that he does not know what testing standards apply to the NK II Revision Stem or any other orthopedic device, and none are cited within the Supplemental Weis Report. Deposition of Philip J. Weis, P.E. ("Weis Dep."), attached as Exhibit C, at 34:18 - 35:26; 75:3-14. Further, Weis not know what guidelines Zimmer's fatigue testing should have met. *Id.* at 108:22 - 110:6. Weis also does not know whether or how Zimmer analyzed fatigue testing results of the NK II Revision System. *Id.* at 110:7-9. Weis does not know how Zimmer's fatigue testing applies to NK II Revisions Stems actually implanted in patients. *Id.* at 110:10-15.

Likewise, despite his criticisms of Zimmer's testing in the Supplemental Campbell Report, Campbell cannot identify any particular industry or other standard that applied to Zimmer's testing and design of the NK II Revision System. Deposition of William B. Campbell, Jr., ("Campbell Dep."), attached as Exhibit D, at 160:20-23; 163:16-19. He also does not know whether Zimmer followed any industry or other standards in testing the NK II Revision Stem, and does *not* opine that Zimmer deviated from any such standard. *Id.* at 161:5-10.[4] Campbell does not hold the opinion that Zimmer's testing was somehow defective:

> Q: Exhibit 15 contains the opinion that the product at issue was not subject to adequate development and testing, correct?
>
> A: Well, that's a broad statement.
>
> Q: Do you agree with it?

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[3] The Court will recall that despite Zimmer's best efforts, Campbell and Weis were not made available for their depositions until July 22 and July 23, 2008, which was after Zimmer's deadline for filing the Motion.

[4] In his deposition, Campbell asserted that Zimmer should have performed fatigue testing of the NK II Revision Stem at a variety of locations, depending on the length of the stem, instead of consistently testing at a lever arm of 2.9 inches. Campbell Dep. at 144:1-21. Campbell also was critical of the rate at which Zimmer applied cyclic loads during fatigue testing. *Id.* at 145:12-15. However, Campbell offers no alternatives to either testing technique and could identify no manufacturer who tested differently.

A: I have no basis to agree with it.

Q: Okay. So you neither agree or disagree, correct?

A: I mean, prior to being placed on the market goes back in time, and I have no evidence, no basis to do that.

Q: Okay. So as you sit here today you don't hold the opinion that the product was not subject to adequate development and testing prior to being placed in the market, correct?

A: I have no basis to say that, no.

Q: Okay. Would you agree that as you sit here today you do not hold the opinion that a lack of adequate testing and development prior to being placed in the market would have eliminated material fatigue failures?

A: I have no basis to make that statement one way or the other.

Campbell Dep. at 242:1-23.

While the Supplemental Campbell Report states that fatigue fractures during Zimmer's fatigue testing of the NK II Revision Stem should have caused Zimmer to take unidentified "adequate steps to prevent this design flaw," Campbell conceded that the very goal of fatigue testing (including Zimmer's testing) is to apply cyclic loads to a device until it fatigues, and that a fatigue failure during testing does *not* mean the subject device is defective. *Id.* at 148:17 - 149:1; 150:22 - 151:2. Campbell also noted that if the loads and cycles are greater in a fatigue test than they are in clinical use, and the device fails during fatigue testing, it does not mean the device is defective. *Id.* at 151:16-25.

Contrary to the statement in the Supplemental Campbell Report that Zimmer's testing was "deficient" because there is "no indication" that Zimmer followed the ASTM standards, neither the Supplemental Reports nor Campbell by deposition identify a single standard in place in 1998 that Zimmer failed to follow. Supplemental Reports, *passim*; Campbell

Dep. at 160:20-23. Campbell also fully admits that "Zimmer's testing is absolutely typical of what we have in the industry," Campbell Dep. at 158:3-5, and he could identify no orthopedic device manufacturer that tested its knee implants differently than Zimmer did in 1998. *Id.* at 159:11-14. Moreover, even though Campbell suggests that Zimmer should have changed the design of the NK II Revision Stem in some respect because the NK II Revision Stem failed in testing when subject to critical fatigue loads, Campbell does not know of any knee implant on the market in 1998 or today that has never failed or that has a better success rate than the NK II Revision Stem. *Id.* at 147:21 - 148:2; 159:15 - 160:1. Likewise, Campbell does not know of any knee stem implant that will not fatigue and fracture. *Id.* at 176:19-25. Ultimately, after being questioned regarding the Plaintiffs' Expert Report and the Supplemental Campbell Report, Campbell testified that he does not have the opinion that Mr. Branche's NK II Revision Stem was defective or unreasonably dangerous in any respect. *Id.* at 209:4-15.

Zimmer's engineering expert, Stephen D. Cook, Ph.D., has evaluated Zimmer's testing and concluded that Zimmer's testing of the NK II Revision System was appropriate in all regards. Supplemental Expert Report of Stephen D. Cook, Ph.D. ("Supplemental Cook Report"), attached as Exhibit E, at 2. Specifically, Dr. Cook explains that Zimmer's fatigue testing applied the loads and cycles generally accepted in the medical industry and by the United States Food and Drug Administration, which approximate patient use and result in successful clinical performance. *Id.* For example, Dr. Cook explained that the 2.9 moment arm was appropriately selected for testing because it represents the location of *in vivo* loading. *Id.* at 3. Zimmer's testing also met all applicable ASTM standards. *Id.*

III. ARGUMENT

Plaintiffs' "negligent testing" or negligent design claim based on Zimmer's testing cannot survive summary judgment. Again, neither the TPLA nor Tennessee common law recognize a cause of action for "negligent testing," and courts of other jurisdictions have held that such a claim is actually a claim for negligent design. *See Stitt v. Philip Morris, Inc.*, 245 F. Supp. 2d 686, 694 (W.D. Penn. 2002) (holding that that no separate cause of action exists for negligent testing; but instead, such claims are subsumed within claims for defective design or failure to warn). Thus, no independent cause of action for "negligent testing" can be said to exist.

Moreover, as the Supplemental Reports and testimony of Campbell and Weis reveal, Zimmer also is entitled to summary judgment on any claim for negligent design based on Zimmer's testing methods for multiple reasons. First, as Zimmer explained in the Motion For Summary Judgment, Plaintiffs' negligent design claim requires Plaintiffs to prove that a defect in the design *proximately caused* Plaintiffs' alleged damages. Regardless of the factual basis for Plaintiffs' negligent design claim – Zimmer's testing or other conduct – Plaintiffs still have no expert medical testimony eliminating Mr. Branche's own deficient femoral bone stock or other medical causes as the proximate cause of the failure of the Device. Statement at 10. For this reason alone, Zimmer is entitled to summary judgment on all of Plaintiffs' claims.

Second, and again as Zimmer explained in the Motion For Summary Judgment, Plaintiffs' negligent design claim requires proof of the existence of a defect, and Plaintiffs possess no such evidence. Because no evidence exists tending to show that a reasonably prudent manufacturer would not have marketed the NK II Revision System following Zimmer's testing or that a reasonably prudent manufacturer would have tested the NK II Revision System differently than did Zimmer, Plaintiffs simply cannot meet their burden of proof.

As Zimmer explained in its Motion For Summary Judgment, the TPLA applies to any claim for injuries or damages allegedly resulting from negligent or defective testing. *See* Tenn. Code Ann. 29-28-102(6). Accordingly, the analysis set forth in Zimmer' Motion demonstrating that Plaintiffs must prove that the Device was defective or unreasonably dangerous in order to recover on any of their claims, applies with equal force to Plaintiffs' recent theory based on Zimmer's testing. *See* Motion at 10-11. As set forth in Zimmer's Motion, under Tennessee law, the "dangerousness" of a complex product – including medical devices – is determined by applying the "reasonably prudent manufacturer" test. *Brown v. The Raymond Corp.*, 432 F.3d 640, 644 (6th Cir. 2005); *Johnson v. Manitowoc Boom Trucks, Inc.*, 406 F. Supp. 2d 852, 857 n.5 (M.D. Tenn. 2006). That is, courts balance the usefulness of the complex product against the degree of risk or danger likely to be caused by the product to determine whether a reasonably prudent manufacturer with knowledge of the usefulness and dangers associated with the product nevertheless would have marketed the product. *Ray ex rel Holman v. BIC Corp.*, 925 S.W.2d 527, 532 (Tenn. 1996); *Ponthieux v. Danek Med., Inc.*, No. 96-3141, 95-2542, 1999 WL 33486689, *5 (W.D. Tenn. May 28, 1999).

Plaintiffs must prove by admissible expert evidence that a reasonably prudent manufacturer would not have marketed the NK II Revision Stem in 1998. *See Johnson*, 406 F. Supp. 2d at 857-58. Plaintiffs cannot meet that burden. Campbell and Weis do not suggest what reasonably prudent manufacturers did (or should have done) when testing knee implants in 1998. To the contrary, the Supplemental Reports include no such opinions. Supplemental Reports, *passim*. Neither Campbell nor Weis is even aware of how orthopedic device manufacturers tested products in 1998 or today. Further, neither expert offers the opinion that Zimmer failed to test as a reasonably prudent manufacturer would test. In fact, Campbell fully admits that he does

not hold the opinion that Mr. Branche's NK II Revision Stem was defective or unreasonably dangerous, or that Zimmer's testing was inappropriate in any respect. Campbell Dep. at 209:4-15, 242:1-23.

Moreover, under the TPLA:

> Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing [or] manufacture . . . shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

Tenn. Code Ann. § 29-28-104. Dr. Cook has explained that Zimmer's fatigue testing was based on industry and FDA standards, as well as clinically-expected results. Supplemental Cook Report at 2, 3. To the contrary, neither of Plaintiffs' experts knows what standards or guidelines Zimmer should have followed with respect to testing the NK II Revision System. *See* Weis Dep. at 75:3-14; 108:22 - 110:6; Campbell Dep. at 163:16-19. And, neither expert knows how Zimmer's tests compare to clinical use of the NK II Revision Stem. Weis Dep. at 110:10-15; Campbell Dep. at 152:3-8. In fact, Campbell specifically stated that Zimmer's testing of the NK II Revision System was "absolutely typical" of testing performed in the medical device industry. Campbell Dep. at 158:3-5.

Where a plaintiff does not have evidence that other manufacturers test differently or rely on a particular set of testing standards, he cannot prove the product at issue was defective or unreasonably dangerous. *Irion v. Sun Lighting, Inc.*, No. M2002-00766-COA-R3-CV, 2004 WL 746823, *16 (Tenn. Ct. App. 2004). Simply put, Plaintiffs cannot demonstrate by admissible expert evidence that a reasonably prudent manufacturer would not have marketed the NK II Revision Stem in 1998. *See Johnson*, 483 F.3d at 429. Without this evidence, Plaintiffs cannot survive a motion for summary judgment. *See Brown*, 432 F.3d at 646.

IV. CONCLUSION

In addition to all of the reasons set forth in Zimmer's Motion, Zimmer also is entitled to judgment as a matter of law on Plaintiffs' claims because Zimmer adequately and appropriately tested the NK II Revision Stem before marketing it. Plaintiffs have no evidence to the contrary, and their theory of negligent or defective testing must fail.

Respectfully submitted,

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CERTIFICATE OF SERVICE

A copy of the foregoing Defendant Zimmer, Inc.'s Supplemental Memorandum Of Points And Authorities In Support Of Motion For Summary Judgment will be made available to the following parties via the Court's electronic filing system:

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